Entergy

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David B. Bice
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Arkansas Nuclear One

0CAN100901

October 13, 2009

ATTN: NRC Document Control Desk
U. S. Nuclear Regulatory Commission
Washington, DC 20555-0001

SUBJECT: Unsatisfactory Laboratory Testing Report
Arkansas Nuclear One – Units 1 and 2
Docket Nos. 50-313 and 50-368
License Nos. DPR-51 and NPF-6

Dear Sir or Madam:

On August 11, 2009, Arkansas Nuclear One (ANO) Fitness for Duty (FFD) Staff received inaccurate test results from blind Quality Assurance (QA) drug testing samples that were submitted to a Health and Human Services (HHS)-Certified Laboratory for analysis.

Three blind QA samples containing target levels of a controlled substance were analyzed by the Quest Diagnostics Laboratory in Lenexa, Kansas. The results of these samples were reported to ANO as invalid. The ANO FFD Staff completed an investigation pertaining to the blind sample errors on September 17, 2009, and pursuant to the reporting requirements of 10 CFR 26.719(c)(1), the investigation results and corrective actions are documented in Attachment 1. Additionally, ANO requested and received an explanatory report from the Lexana Quest Laboratory, which is contained in Attachment 2.

There are no commitments contained in this submittal. Should you have any questions concerning this issue, please contact me.

Sincerely,

DBB/SLC

Attachments: 1. Arkansas Nuclear One - Blind QA Sample Error Investigation Report
2. Quest Diagnostics - Blind Sample Report

A022
NRR

cc: Mr. Elmo Collins
Regional Administrator
U. S. Nuclear Regulatory Commission
Region IV
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Arlington, TX 76011-4125

NRC Senior Resident Inspector
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U. S. Nuclear Regulatory Commission
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11555 Rockville Pike
Rockville, MD 20852

Attachment 1

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Arkansas Nuclear One - Blind QA Sample Error Investigation Report

Identification of Error:

Three blind Quality Assurance (QA) samples that had been certified by the manufacturer to be positive for phencyclidine (PCP) were reported as "Invalid – GC/MS Interference" by the Quest Diagnostics Laboratory in Lenexa, Kansas. The samples, identified as lot number 0906PCP, were purchased from Professional Toxicology, and certified with a target PCP level of 45 ng/ml. They were shipped to the Quest – Lenexa laboratory on August 7, 2009, and were received in the laboratory on August 8, 2009. On August 11, 2009, the results were reported as "Invalid – GC/MS Interference".

Investigation:

Upon discovery of the testing error, a request was submitted to the Quest – Lenexa facility to re-test the samples at the Quest Laboratory in Atlanta, Georgia. The Atlanta laboratory identified the samples as valid, positive for PCP, and quantified PCP at levels of 33-34 ng/ml.

The toxicologist at Professional Toxicology stated that Lot number 0906PCP had initially been certified at the Quest Diagnostics laboratory in Lenexa, and had been independently verified at other Health and Human Services (HHS)-certified laboratories without any interference or other problems being reported.

The toxicologist at the Quest - Lenexa laboratory was notified of the irregularity. He stated that the laboratory had initially quantified PCP at levels of 40-41 ng/ml. However, one of the validation values was outside the range allowed by the laboratory's QA testing procedures. These values are required to be within a predetermined range in order to certify the results as valid. Since one of the values was outside the allowed range, the results could not be reported as positive for PCP. Instead, the laboratory reported the results as "Invalid – GC/MS Interference".

Quest - Lenexa continued to evaluate the samples in an attempt to identify interfering agents. Two additional tests were performed on the remaining sample. Since the quantity of the remaining sample was limited, the samples were diluted to ensure a sufficient quantity for testing. Specimen dilution is a common laboratory process used when the quantity of a sample is limited, or when previous testing produces results outside the linear reporting capabilities of the testing methodology. On re-test, the results were found to be valid, and PCP was quantified at 35-36 ng/ml.

Toxicologists from Professional Toxicology and Quest – Lenexa were then engaged in a group discussion with the Arkansas Nuclear One (ANO) Access Authorization/Fitness-For-Duty (AA/FFD) Supervisor, and the ANO AA/FFD Senior Coordinator, to attempt to establish a cause for the discrepancy. Although possibilities were discussed, no probable causes could be determined. An additional aliquot of lot number 0906PCP was forwarded to Quest – Lenexa for processing in an attempt to identity an interfering agent via Gas Chromatography/Mass Spectrometry (GC/MS). No such agent was discovered, and the laboratory was successful at quantifying PCP levels at 35 & 36 ng/ml in two separate tests.

In summary, specimens from Professional Toxicology lot number 0906PCP were processed on five different occasions at two different laboratories. Four tests were performed at the Quest – Lenexa laboratory, and one test was performed at the Quest – Atlanta facility. On four occasions the results were found to be valid and positive for PCP. On one occasion, the results quantified PCP level at

40-41 ng/ml on all three samples, but the Quest – Lenexa laboratory was unable to report these results as positive for PCP because the QA validation values were outside the acceptable range.

Cause:

Since expected results were obtained in four of the five instances, there appears to be a low probability of irregularity in the specimens. The cause of the discrepancy appears to be an unexplained anomaly in the laboratory's QA validation process.

Corrective Actions:

On September 17, 2009, the ANO AA/FFD Staff completed an investigation which is documented in Entergy's corrective action process. As stated in the investigation, the Quest - Lenexa Laboratory could not conclusively explain the unsatisfactory test results; however, the samples in question were successfully re-tested at the Quest Laboratory in Atlanta, Georgia. ANO AA/FFD requested and received a formal written response from the Quest – Lexana Laboratory staff regarding the sampling error. Additionally, other plants within the Entergy fleet were notified of the Quest-Lenexa reporting error.

Attachment 2

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Quest Diagnostics - Blind Sample Report

Quest Diagnostics Incorporated

10101 Renner Blvd.
Lenexa, KS66219
800.873.8845
www.questdiagnostics.com

Quest
Diagnostics

October 8, 2009

Jerry Woods
Sr. Coordinator, Security
Access Authorization / Fitness for Duty / Medical
Entergy Operations, Inc. / Arkansas Nuclear One

RE: Urine Specimen ID Numbers 0566242, 0566251 and 0566241

Dear Mr. Woods:

The Quest Diagnostics Employer Solutions laboratory in Lenexa, Kansas received three different specimens, identified above, on August 8, 2009. Based on our conversations, I understand they were all portions of the same lot of a Blind Quality Control urine specimen, identified by you, as lot# 0906PCP. The specimens were received and processed according to our Standard Operating Procedure (SOP). The specimens were initially tested by immunoassay. The specimens screened presumptively positive for phencyclidine (PCP) and were reflexed for confirmation testing.

The confirmation procedures were performed according to our SOP with analysis by Gas Chromatography/Mass Spectrometry (GC/MS). The calibrators and controls met acceptability requirements according to the SOP. However, the ion-ratios for the target compound (PCP) were out of range – internal standard ion-ratios were in range – in all three specimens and, therefore, did not meet acceptability criteria. The quantitative results were 40, 41 and 40 ng/mL respectively. According to the SOP, the confirmation test was repeated.

The second confirmation test was performed on an additional portion of each of the original specimens. The test was performed again according to our SOP. The specimens were tested at a two-fold dilution. The calibrators and controls met acceptability requirements according to the SOP. However, the three specimens listed above again had ion ratios for the target compound outside of the acceptable range. The quantitative results were 42, 44 and 45 ng/mL, respectively.

The specimens were reported as "Invalid" according to our SOP.

The specimens were retested at your request on August 19 at a two-fold and four-fold dilution using our confirmation procedure. All calibrators and controls met acceptability requirements according to the SOP. The ion ratios of the specimens were acceptable. Quantitation of the specimens ranged from 31 – 36 ng/mL.

A bottle of lot #0906PCP was received by the lab from your facility and tested by GC/MS confirmation on September 4, 2009. The urine was tested undiluted and at a two-fold dilution. All calibrators and controls met acceptability requirements according to the SOP. The specimens were also acceptable with quantitative results of 37 and 34 ng/mL, respectively.

Please let me know if I may help further in this or any other situation.

Sincerely,

Lance Presley, Ph.D., DABFT
Laboratory Director